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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

JOHNSON, JERROLD D

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,629

Applicant(s)

DELANEY ET AL.

Examiner

Jerrold Johnson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 22-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims set forth details of embodiments that are patentable distinct from those originally claimed and disclosed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

During a telephonic conversation with Patrick Fay on 06 September 2006, Mr. Fay indicated that the original disclosure was deficient in the disclosure of the subject matter set forth in these claims.

Claim Rejections - 35 USC § 102 and 35 USC § 103

The text of these two statutes has been previously presented in this Application.

1. Claims 1-9, 12, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman US 6,569,106.

Re claim 1, Ullman discloses in Fig. 4 a protective package for an elongated medical device, comprising:

a protective sheath 27 including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening disposed between the first and second ends of the sheath.

Re claim 2, the sheath is formed as a hoop and wherein the medical device is a catheter. Note Col. 3 lines 29 and 30. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Ullman to accommodate.

Re claim 3, a protective assembly 18 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 30 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

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Re claim 5, an adapter 30 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device, through the size of the funnel shaped opening 18, which would accommodate the distal end.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 8, the sheath is adapted to contain a catheter with a shaped distal tip. Again, reference is made to the funnel opening, which may or may not be needed to accommodate a shaped distal tip, as the shaped distal tip of some catheters is of a size that approximates the size of the remainder of the catheter, as is shown in Talonn.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening appears to be oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 15, Ullman discloses a catheter kit comprising
a catheter having a shaped distal tip;

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a tubular enclosure 27 having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter;

a first end of the tubular enclosure 18,21 being adapted to receive the shaped distal tip;

a second end of the tubular enclosure being adapted to receive a proximal end of the catheter, and

a hydration opening 30 extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.

Re claim 16, a protective structure 18,21 is disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip.

Re claim 17, the tubular enclosure is coiled to form a hoop.

With respect to Applicant's arguments, firstly, the arguments address alleged deficiencies of the disclosure of Ullman in Fig. 1, when the rejection clearly sets forth the specific embodiment of Fig. 4. Additionally, Applicant has also ignored the recitation of Col. 3, lines 29 and 30, which were set forth in the rejection, and which address the applicability of the invention to accommodate catheters.

Applicant's argument that the device of Ullman is not a sheath is noted, but also found to be non-persuasive. Merriam-Webster's Collegiate Dictionary, tenth edition, sets forth the following definition of sheath: any of various covering or supporting structures that are applied like or resemble in appearance *or function* (italics added) the

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sheath of a blade. Clearly Ullman discloses a structure which meets the definition, particularly with respect to the function of a sheath of a blade.

Applicant's arguments drawn to Ullman not being adapted to receive the shaped distal tip are noted, but this argument was addressed in the previous rejection a portion of which is provided again below:

"Re claim 1, Ullman discloses in Fig. 4 a protective package for an elongated medical device, comprising:

a protective sheath 27 including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening disposed between the first and second ends of the sheath.

Re claim 2, the sheath is formed as a hoop and wherein the medical device is a catheter. Note Col. 3 lines 29 and 30. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Ullman to accommodate."

Applicant's arguments directed to the "tip 16a is never received by the chamber 13" are noted, but not persuasive. The claim recites a first end adapted to receive a distal end... and a second end adapted to receive a proximal end. The rejection addresses these broad recitations. The recitation "adapted to receive" does not set forth a specific arrangement that is not disclosed by Ullman. The adapted to receive

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recitation does not set forth with any specificity exactly how the ends are received. And, although Ullman in his disclosure of accommodating a guidewire suggest leaving a portion of the guidewire extended from the sheath, that in no way suggests that the sheath is not *suitable* to accommodate the guidewire. Clearly the lumen of Ullman is *suitable* to receive the entire guidewire, if desired. For example, were the end of the guidewire disposed entirely within the conical funnel, it would thus be *received* in the funnel, and accordingly, would meet the claim language. Additionally, were Ullman accommodating catheters, as he suggests, the same situation would be present. In the funnel portion is configured such that in both of these situations (guidewire or catheter) the funnel portion is suitable to receive the end of the guidewire or catheter entirely within the funnel portion, and yet still allow easy removal of the guidewire or catheter from the package.

Finally, with respect to Ullman not disclosing a “hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.” Clearly, from Fig. 4, fluid entering into the port 30 will go “toward the first and second ends”, as both ends are below the port 30. However, even if the first end 26 were higher than port 30, which it is not, and no fluid went toward the first end, the claim limitation would still be met. Claims 9 and 15 recite: a “hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends”, if the proportion is all the fluid directed to one end and none of the fluid directed to the other end, the claim limitation is met.

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2. Claims 1-7, 9-14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuels US 6,588,588.

Re claims 1 and 21, Samuels discloses a protective package for an elongated medical device, comprising:

a protective sheath including a lumen sized (so as to be inherently capable) to receive a body of the elongated medical device (as well as to be inherently capable to tightly fit a body of the elongated medical device), wherein a first end of the sheath 42 is adapted to receive a distal end of the elongated medical device and a second end of the sheath 46 is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 10 disposed between the first 42 and second 46 ends of the sheath.

Re claim 3, a protective assembly the inside of the luer 10 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 10 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, an adapter 10 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

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Re claim 9, the hydration opening 10 is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 10, the desired ratio is one to one. The one to one ratio is achieved as the flow of fluid into the first end will necessarily flow through the second end, as the ends are connected.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end. The flow is initially directed toward the first end 42, but thereafter the desired ratio of fluid flow at the first end and second end will be equalized as the fluids flow through the sheath toward the other ends, achieving one to one flow upon the filling of the sheath.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 14, the desired ratio is one to one.

Applicant's arguments with respect to Samuels are noted but are also not persuasive. Samuels does in fact disclose an opening 30 suitable to perform the intended use as a hydration opening. Samuels in US 6,375,006 clearly provides the extrinsic evidence that one of ordinary skill art would find the hydration opening of Samuels 30 suitable for the intended use as a hydration opening.

3. Claims 8, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels US 6,588,588 in view of Ullman.

Samuels, as stated above, discloses the claimed features of claims 1-7 and 9-14, but does not disclose his package being used with a catheter.

Samuels further discloses the structure of the package as claimed with the sheath being formed as a hoop but does not disclose the medical device is a catheter.

Again, Ullman discloses in col. 3 lines 29 and 30 the use of a guidewire package being used to protect and hydrate catheters.

It would have been obvious to one of ordinary skill in the art to modify the package of Samuels, as Ullman suggests, to accommodate catheters. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Samuels to accommodate a catheter. There are inherent benefits brought on when the uses of an item, such as is disclosed by Samuels, are increased, as would be the case upon the slight modification of the package of Samuels suggested by Ullman.

Additionally, the sheath of Samuels would easily be adapted to contain a catheter with a shaped distal tip upon the modifications as taught by Ullman. Again, reference is made to the catheter of Talonn. Modifications may or may not be needed to accommodate a shaped distal tip in many catheters, like that disclosed by Talonn. This is because the shaped distal tip of some catheters, such as is disclosed by Talonn, are of a size that approximates the size of the remainder of the catheter.

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Additionally, upon the filling of the sheath of Samuels with fluid, the proximal and distal ends are substantially equally hydrated. And, as was previously stated, the hydration opening is equidistant between the first and second ends.

With respect to Applicant's arguments addressing this rejection please note the response above.

4. Claims 1,3,6-9,12,13,15,16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi US 3,861,395.

Re claim 1,15 and 19, Taniguchi discloses (best seen in Figs. 1 and 3) a protective package for an elongated medical device (the micro-catheter), comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening (beneath the reservoir 31, as seen in Fig. 3) disposed between the first end not identified and second 22 ends of the sheath. The proximal end 66 of the catheter is shown being extended past the second end 22 during use in Fig. 1, and recessed behind the second end 22 in Fig. 3).

Re claim 3, a protective assembly (not identified) is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 6 and 16, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

With respect to Applicant's arguments, the Examiner set forth in the rejection the interpretation of Taniguchi as having:

a hydration opening (beneath the reservoir 31, as seen in Fig. 3) disposed between the first end not identified and second 22 ends of the sheath. The proximal end 66 of the catheter is shown being extended past the second end 22 during use in Fig. 1, and recessed behind the second end 22 in Fig. 3).

Applicant's arguments do not address this interpretation and are not understood by the Examiner. Clearly in Fig. 3, the hydration opening (beneath the reservoir 31, as seen in Fig. 3) is disposed between the first end of the sheath (the closed end of the bag, which is not identified) and the second end 22 of the sheath.

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5. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi US 3,861,395 in view of Hodgkins US 4,805,611.

Taniguchi discloses the claimed features but does not disclose a luer or adapter capable of receiving a syringe.

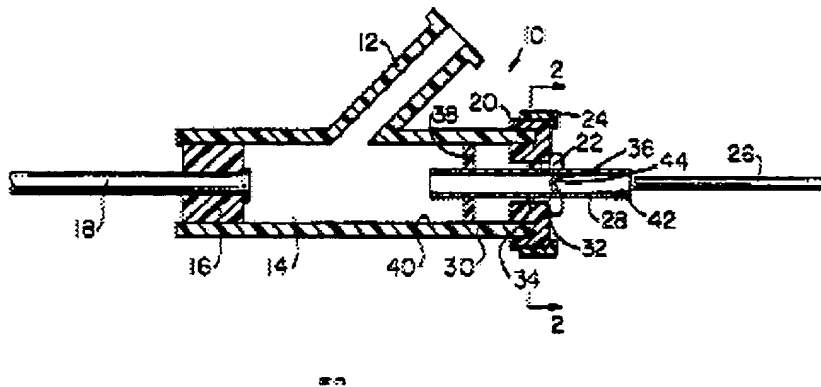
Hodgkins discloses a luer or adapter 67 capable of receiving a syringe.

It would have been obvious to one of ordinary skill in the art to modify the sheath of Taniguchi with the much simpler construction of an irrigation port as taught by Hodgkins so as to allow the use of syringes to administer a desired amount and type of irrigation compound or lubricant.

6. Claims 1,3-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinberger US 6,258,072.

Re claim 1, Weinberger discloses on the first page of the patent a protective package capable of accommodating an elongated medical device, comprising:

a protective sheath including a lumen of a size that is capable to receive a body of the elongated medical device (not shown), wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and



a hydration opening 12 disposed between the first and second ends of the sheath.

Re claim 3, the rigid sheath is suitable for the purpose of providing protection to distal ends of an elongated medical device. Accordingly, the first end of the sheath could be considered a protective assembly.

Re claim 4, a luer 12 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, the luer 12 is suitable as an adapter to receive a syringe.

Re claim 6, the protective assembly (the first end) is suitable to protect and prevent damage to a curvature of a distal end of an elongated medical device.

Re claim 7, the sheath is suitable for containing one of a catheter, guide wire or medical coil.

Re claim 8, the sheath is suitable to contain the shaped distal tip of a catheter.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Re claims 12 and 13 note the angled orientation of luer 12.

Regarding Applicant's arguments, it is noted that the claim 1 does not stipulate that the first and second ends are adapted to receive the ends of the elongated medical device simultaneously.

7. Claims 1,3-9,11-13,15,16,19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Colliver et al. US 5,427,114.

Re claim 1, Colliver discloses on the first page of the patent a protective package capable of accommodating an elongated medical device (internal catheters 30 and 32), comprising:

a protective sheath including a lumen of a size that is capable to receive a body of the elongated medical device, wherein a first end of the sheath 18 is adapted to receive a distal end of the elongated medical device and a second end of the sheath 28 is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 14 disposed between the first and second ends of the sheath.

Re claims 3,6 and 8, the protective first end of the sheath 28 is suitable for providing protection to maintain the shaped (curved in cross-section) distal end of catheter 20 (see Fig. 3).

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Re claim 4, a luer 14 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, the adapter (end of luer 14) is suitable for receiving a syringe.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 11, the hydration opening is substantially equidistant from the first end 18 and second end 28.

Re claims 12 and 13 note the angled orientation of luer 14.

Re claim 15, note the rejection of claim 1.

Re claim 16, both ends 18 and 28 protect the curvature (cross-sectional) of the distal and proximal ends of the internal catheters.

Re claim 19, again, as no definition is provided for a "micro-catheter", catheters 30 and 32 meet this limitation.

Re claim 20, the hydration opening is equidistant between the first and second ends 18 and 28.

Regarding Applicant's arguments, it is noted hermetic seal prevents infused fluid from entering into the catheters, but does allow the fluid to flow within the sheath outside the catheters 30,32.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JDJ



Mickey Yu
Supervisory Patent Examiner
Group 3700